REMARKS

Claims 1-11 remain pending in the application. Only claim 1 is in independent form.

Claims 1-11 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter Applicant regards as the invention. Specifically, claim 1 is identified as failing to explicitly state that the increased dissolution rate associated with the present invention is relative to the same drug in bulk form having the same size. Accordingly, Applicant has amended claim 1 as suggested in Paper No. 18 to now recite that in comparison to a drug in a bulk powder form, the bulk drug is "of a dimension the same as the drug particle." Accordingly, Applicant respectfully submits that all the rejections under 35 U.S.C. §112, second paragraph, have been overcome.

Claims 1-11 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Amidon et al. (U.S. Patent 5,834,022) in view of Woo (U.S. Patent 5,589,455) and Gennaro et al. (Remington's Pharmaceutical Sciences, 18th Edition, 1990, pp. 1662-1664).

Applicant notes with appreciation the withdrawal of prior rejections under 35 U.S.C. §112, first paragraph.

Remarks Directed to Rejection of Pending Claims Under 35 U.S.C. §103(a)

The statement of the basis of the rejection and the comments made of record by way of the amendment filed 15 May 2003 are incorporated herein by reference.

In addition to the remarks of record, Applicant submits that the prior art combination fails to function as does the claimed invention.

The claimed invention is submitted to encompass the specific relationship between drug vehicle components in order to optimize insoluble drug dissolution rates. Applicant has herein neither taught nor claimed a new active drug component, a new matrix material nor

drug solubilizing agent. Rather, Applicant has identified an encapsulant for a drug particle as detailed in Figures 1 and 2 in the corresponding specification text of the instant application that relates to optimizing dissolution rates. Applicant's usage of a mathematical expression is submitted not to render the point of novelty merely in functional language but rather define a dimensional relationship between a drug particle to the thickness of a coating thereon composed of the matrix and solubilizing agent. Further, Applicant submits that the insertion of values into the expression found in pending claim 1 is well within the knowledge of one skilled in the art and indeed to a great extent found in well-known treaties such as Remington's Pharmaceutical Sciences (reference of record).

The criticality of the claimed relationship and the surprising result from the practice thereof is submitted to be readily demonstrated with reference to Woo. Woo has been cited by the Examiner for teaching a microemulsion to enhance the solubility of the poorly soluble drug cyclosporin, with reference made to the teachings found in particular within the abstract and column 4, line 53 – column 7, line 13. (Paper No. 14, page 6; and reiterated in Paper No. 18, page 4). Woo teaches a fairly complex chemistry between cyclosporin, polyethylene glycol, a mixture of an esterified fatty acid-primer alcohol, medium fatty acid triglyceride, fatty acid monoglyceride and a surfactant having an HLB value of 10 to 17 (column 4, line 67 – column 5, line 6) in order to improve cyclosporin solubility. Woo further goes on to teach that conventional adjuvants, excipients and additives conventional to soft capsules can be added which include lecithin and gelatin (column 6, lines 57-64).

In contrast to Woo, the present invention is able to achieve the same, if not superior, solubility merely with conventional capsule components of lecithin and gelatin. The fact that Woo resorts to such a chemistry to increase cyclosporin solubility is submitted to be direct

evidence of the nonobviousness of improving drug solubility with conventional capsule components per dependent claims 5 and 9.

The court has stated that:

> A combination may be patentable whether it be composed of elements all new, partly new, or all old. *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984).

The prior art reference combination nowhere teaches the criticality of adjusting the relative dimensions of a solid drug particle relative to a surrounding coating of matrix and solubilizing agent per the expression of claim 1. Considering the numerous commercial products available to enhance drug dissolution, as well as the enormous compositional variation in a multi-component system, as exemplified by Woo, the identification as per claim 1 of a specific compositional relationship once the identity of the drug and agents is chosen represents an optimal point and precludes near infinite and haphazard experimentation. As such, Applicant submits that the identification of an optimal drug delivery vehicle upon user selection of a given drug, matrix and solubilizing agent is by definition nonobvious in light of the prior art of record. As none of the references of record, namely Amidon et al., Woo or Gennaro et al., alone or in combination, teach insoluble drug dissolution rate optimization by satisfying the relationship of pending claim 1 without resort to compositional range experimentation, Applicant submits that the pending claims are in fact nonobvious over the prior art reference combination of record and withdrawal of the rejection of claims 1-11 under 35 U.S.C. §103(a) is thereby solicited.

Summary

Claims 1-11 are the claims pending in this application. Entry of this amendment is requested. Reconsideration and allowance of the claims is also solicited. If the Examiner finds to the contrary, it is respectfully requested that the undersigned in charge of this

application be called at the telephone number given below in order to resolve any remaining issues.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 07-1180.

Respectfully submitted,

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